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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,776	05/10/2002	Jean-Jacques Goupil	2-1032-187	6106
803	7590	06/03/2004	EXAMINER	
STURM & FIX LLP 206 SIXTH AVENUE SUITE 1213 DES MOINES, IA 50309-4076			CHANNAVAJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,776	GOUPIL, JEAN-JACQUES	
	Examiner	Art Unit	
	Lakshmi S Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 12-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4-30-02</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Claims 1-11 have been canceled. Claims 12-25 are presented for prosecution.

Instant claims are directed to a composition comprising 5-methoxypsoralen (5-MOP), the concentration in the composition being adjusted by adding a suitable amount of bergaptene-free natural citrus (bergamot) essence. Dependent claims 13-15 recite specific amounts of 5-MOP.

Claim 17 recites the composition in the form of a milk, spray etc. Claims 18-23 recite organic or inorganic sunscreens. Claim 24 requires no chemical screening agent. Claim 25 recites maximum screening index of 12.

Specification

1. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

2. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd.

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App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 25 recites the broad recitation that screening index of a maximum 12, and the claim also recites maximum of 10, which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

3. Claims 12-18, 21-23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 586282 (EP).

EP discloses compositions containing 5-MOP for treating dermatoses such as vitiligo, para-psoriasis etc. Examiner notes that EP reference is a French document and that US 5,962,512 ('512) belongs to the same patent family. Accordingly, examiner relies on the US patent for identifying the teachings that read on the claimed components.

EP discloses 5-MOP added in the form of natural essence of bergamot, in the amount of 60-100 ppm (US '512- col. 2, lines 19-26). Thus, EP discloses subject matter of claims 13-16. EP discloses the composition in the form of oil ('512-col. 2, lines 1-3) and reads on claim 17. The topical composition of EP further contains claimed organic sunscreen agents ('512- Table in col. 2), in the same amount. Thus, EP discloses subject matter of claims 18, 19 and 21-23.

With respect to the claim limitation “the 5-MOP concentration is adjusted by adding bergaptene-free bergamot essence”, instant claim recites only a composition containing 5-MOP. The limitation that the concentration is adjusted using bergaptene-free bergamot reads on the

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process of preparing the composition i.e., a product by process. It is to be noted, "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Further, instant specification describes that the 5-MOP concentration of natural citrus essence is not constant and may vary depending on the particular species. Furthermore, it is not possible to distinguish the instant composition (produced by claimed adjustment) from the prior art compositions upon mixing 5-MOP and 5-MOP free citrus essence, as one cannot differentiate 5-MOP containing citrus oil as opposed to 5-MOP free citrus oil. Instant claim 25 recites a maximum screening index. Since the product of EP is the same as that of the instant claims (for the reasons mentioned above), the screening index is inherent to the product. Therefore, EP anticipates instant claims.

4. Claims 12-14, 16-18, 21-23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,699,781 to Goupil.

Goupil discloses sun products comprising a natural bergamot essence containing 5-MOP, a UV-B filter (organic sun screening agent), both incorporated in an oily excipient. Goupil does not disclose the method of adjusting the concentration of 5-MOP as claimed. However, as mentioned above, instant claim 12 reads on a product claim and further, the amount of 5-MOP

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taught by Goupil (27.5 mmg per 100 g of sun product) equals to 2.75 ppm, which is still within the range of the instant claims 13 and 14. Accordingly, Goupil anticipates instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 586282 (English equivalent US 5,962,512).

Claim 24, dependent from claim 12, recites that the composition is free of screening agent. EP teaches compositions containing 5-MOP for the treatment of psoriasis and other dermatoses such as para-psoriasis, eczema, vitiligo etc. While EP suggests a combination of 5-MOP and UVB filters, adding or deleting UV-B filters to the composition containing 5-MOP and still achieve the therapeutic effect in treating psoriasis or eczema or other dermatological conditions would have been obvious for one of an ordinary skill in the art would because the EP teaches 5-MOP as the primary active agent in treating the above dermatological conditions. Accordingly, one of an ordinary skill in the art would have expected to provide effective treatment to psoriasis and other dermatological conditions with a composition containing 5-MOP even in the absence of sunscreen agents.

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6. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,699,781 (Goupil) in view of 5,614,197 to Pathak et al (Pathak).

Instant claims recite inorganic sunscreen agents such as titanium oxide and zinc oxide. Goupil teaches organic sunscreen agents but not inorganic agents as claimed. However, Goupil suggests that other beneficial agents such as additional sunscreen agents may be added to the 5-MOP and UV-B filter containing compositions.

Pathak teaches methods and compositions for use in photoprotection of skin, comprising polypodium extracts together with physical and chemical sunscreen agents (abstract). Among the physical sunscreen agents, Pathak teaches titanium dioxide, zinc oxide (col. 10, lines 13-29). Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add titanium dioxide or zinc oxide of Pathak, in the composition containing 5-MOP and UV filtering agents of Goupil because Goupil desires addition of other sunscreen agents which are beneficial to skin and Pathak suggests that the physical sunscreens act to reflect and/or diffract and/or scatter UV radiation. Accordingly, a skilled artisan would have expected to increase the photoprotection of the composition of Goupil by adding the physical screening agents of Pathak.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

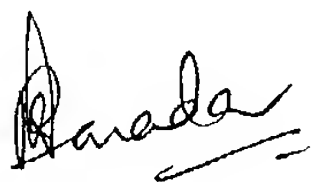
7. Claims 12-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-11 of U.S. Patent No. 5,962,512. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims recite a method of treating dermatoses as well as a composition, wherein the composition in both the method and composition claims comprise natural citrus essences and 5-MOP in an amount between 75 to 100 ppm. Claim 10 of the patent further recites sunscreen agents such as those claimed in the instant. The amount of 5-MOP claimed in the patent is in the same range as that claimed. Patented claims do not state the instant limitation that 5-MOP concentration is adjusted by the addition of bergaptene-free natural citrus essence. However, the limitation reads on the process of preparing the composition i.e., a product by process. It is to be noted, "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production (see above). Further, applicants state in the instant specification that the amount of 5-MOP in natural citrus is not constant and varies. Accordingly, irrespective of how the amount of 5-MOP is adjusted or employed in the patent compositions, the patented composition reads on the instant composition.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615
June 1, 2004